K003075

DEC 1 1 2001

Nellcor Puritan Bennett *KnightStar*® 330 Ventilator 510(k) Summary

1. Submitter Information

Manufacturer:	Nellcor Puritan Bennett Inc. (a subsidiary of Mallinckrodt Inc.) 2800 Northwest Blvd. Minneapolis, MN 55441
Contact:	Darin Busch (same address as above) Tel: 763-694-3563 Fax: 763-694-3600 darin.busch@mkg.com

2. Device Information

Proprietary Name:	*KnightStar*® 330 Ventilator
Common Name:	Bi-Level Ventilator
Classification Name:	Continuous Ventilator, Minimal Ventilatory Support 21 CFR 868.5895, Class II, 73 MNT

3. Predicate Device

The KS330 bi-level ventilator is predicated on the Nellcor Puritan Bennett *KnightStar*® 335 Respiratory Support System, originally cleared by FDA per K942210 for the treatment of respiratory insufficiency and obstructive sleep apnea (OSA). Clearance for the extended indication of respiratory failure was granted by FDA in 1998 under K973004 without any design changes to the ventilator, just limited labeling changes and the required use of an external airway pressure monitor. The KS330 indications for use are identical to those of the KS335 predicate. Its feature set and performance specifications are substantially equivalent.

4. Device Description

The KS330 is a blower based, bi-level positive pressure ventilator system. It provides the patient with positive airway pressure in order to open the nasal passages to augment breathing. The device delivers pressures from 3 to 30 cmH_2O. It offers ramp and delay features which allow the patient to fall asleep faster and more comfortably.

Powered from either AC mains or an external battery, the KS330 operates in three different modes: CPAP, I/E PAP and Assist/Control. In CPAP mode, the user prescribes a pressure from 3 to 20 cmH_2O to be delivered continuously (single level). I/E PAP mode allows different inspiratory and expiratory pressures to be delivered (bi-level). The expiratory pressure is lower than the inspiratory pressure to reduce work of breathing and increase patient compliance. Assist/control mode provides bi-level pressure delivery with a prescribed I:E ratio and a minimum backup ventilatory rate. Pressure range for the two bi-level modes is 3 to 30 cmH_2O.

Since the device is considered as a critical care ventilator, it has a comprehensive alarm set. Alarm temporal characteristics and visual indicator colors distinguish between high and medium priority conditions. Selected audible alarms may be muted and/or reduced in intensity. Low pressure, circuit leak, power loss and internal device malfunction are designated as high priority alarms requiring immediate attention. A high pressure condition initiates a medium alarm since design controls preclude delivery of excessive pressure.

5. Intended Use

The KS330 is intended to non-invasively treat spontaneously breathing patients weighing 30 kg or more who suffer from respiratory insufficiency and/or obstructive sleep apnea in home, hospital or institution settings. It may also be used in the treatment of respiratory failure in hospital or institution settings.

6. Technology Characteristics Comparison

Both the KS330 subject device and the KS335 predicate device are blower-based ventilators. Airflow and pressure are delivered to the patient by a rotating impeller wheel. Impeller speed is controlled by employing a closed-loop feedback system. Both devices contain a pressure sensor which allows the delivered pressure to be compared to the set target value, thereby increasing or decreasing rotational speed accordingly. The two designs differ in that the pressure is sampled at the patient interface on the KS330 versus at the blower outlet on the KS335. Proximal sensing at the patient interface allows the KS330 to provide improved pressure regulation and accuracy.

The blower designs and motor feedback mechanisms differ significantly between both devices. The KS330 employs a single-stage blower where the motor is directly controlled by the microcontroller, whereas the KS335 uses a three-stage blower controlled by a motor control chip in conjunction with its microcontroller. The KS330 impeller is small and lightweight and therefore has low inertia. It can respond rapidly to acceleration and deceleration actions by the variable-speed AC motor. Motor control feedback is provided by firmware. In contrast, the KS335 predicate device uses a DC motor to rotate a larger, heavier impeller wheel at a relatively constant rate. Pressure regulation and changes are facilitated through hardware control of two mechanical butterfly valves which open and close alternately via a rotary actuator to

either decrease or increase delivered pressure. The inlet valve allows air to flow to the patient circuit while the dump valve routes air to the outlet and baffle. The same analog breath detection circuitry is incorporated into both the KS330 and KS335 ventilators.

7. Summary of Bench Tests

Ventilator performance tests were conducted in accordance with the requirements of FDA's draft Reviewer Guidance for Ventilators (07/95), Bazaral's CPAP letter RESP-96-9.1 (09/96) and manufacturer specifications. At the time of this submission, the KS330 had undergone more than 1000 of the 2000 required hours of endurance testing per ASTM F 1100-90. All accessories presented in this submittal were tested and qualified for use with the *KnightStar* 330.

Electrical and mechanical safety tests, as well as environmental tests, were successfully completed in accordance with the requirements of FDA's draft Reviewer Guidance for Premarket Notification Submissions (11/93) and IEC 60601-1.

Electromagnetic compatibility (EMC) and electrostatic discharge (ESD) tests were successfully completed in accordance with the requirements of IEC 60601-1-2 plus the unique requirements contained in FDA's draft Reviewer Guidance for Premarket Notification Submissions (11/93) and the draft Reviewer Guidance for Ventilators (07/95).

8. Conclusion

Based on a technical comparison and the results of laboratory and bench tests, the *KnightStar* 330 Ventilator is substantially equivalent to the *KnightStar* 335 predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2001

Mr. Anthony M. Mullin
Mallinckrodt, Inc.
675 McDonnell Blvd.
Bldg. 10-2-N
St. Louis, MO 63134

Re: K003075
KnightStar® 330 Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II (two)
Product Code: 73 MNT
Dated: September 12, 2001
Received: September 14, 2001

Dear Mr. Mullin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

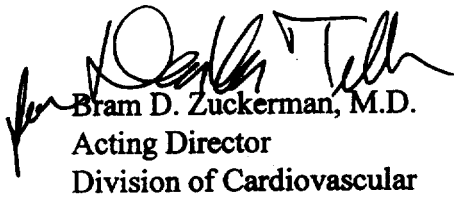
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K003075

Device Name: *KnightStar*® 330 Ventilator

Indications for Use:

The *KnightStar*® 330 Ventilator is indicated for use in treating obstructive sleep apnea and respiratory insufficiency in the home, hospital or institution settings. The device may also be used to treat respiratory failure in hospital or institution settings. The device is intended for non-invasive treatment of spontaneously breathing patients weighing at least 30 kg.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Y

Over-The-Counter Use ____

Division of Cardiovascular & Respiratory Devices
510(k) Number K003075